K040419 1/3

MAR 2 5 2005

510(k) Summary

IsoTis OrthoBiologics DynaGraft II

1. Sponsor

IsoTis OrthoBiologics, Inc.
2 Goodyear, Suite B
Irvine, CA 92618
U.S.A

Contact Person: Paul Doner
Telephone: 949 855-7168
Facsimile: 949 595-8711

Date Prepared: March 2005

2. Device Name

Proprietary Name: DynaGraft II Gel and Putty
Common/Usual Name: Bone Void Filler
Classification Name: Sec. 888.3045 Resorbable calcium salt bone void filler device.

3. Predicate Devices

AlloMatrix ® DBM Putty with inert carrier Sodium Carboxymethylcellulouse (K040980)
InterGro® DBM with inert carrier Lecithin (K031399)

4. Device Description

DynaGraft II is derived from selected donated human bone tissue that has been processed into particles. The bone particles are subsequently demineralized using a hydrochloric acid process. The demineralized bone matrix (DBM) is combined with an inert reverse phase carrier and formulated to a gel or putty-like consistency.

The carrier is a solution of polyethylene oxide polypropylene oxide block copolymer dissolved in water exhibiting reverse phase characteristics (i.e., an increase in viscosity as temperature increases).

5. Intended Use

For orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. DynaGraft II is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine, and pelvis) and as a bone void filler of the extremities and pelvis. These defects may be surgically created or the result of traumatic injury to the bone.

6. Technological Characteristics and Substantial Equivalence

DynaGraft II and its predicate devices are similar in design, materials of construction and function. The proposed and predicate devices are osteoconductive and osteoinductive. The DynaGraft II product and its predicate devices provide an interconnected, porous scaffold and an environment for new bone ingrowth and stimulate bone growth. All products are provided sterile and for single patient use. The only difference between the proposed device and its predicates are the inert carriers used. The donor bone in the DynaGraft II product meets the requirements of the AATB. Product safety and effectiveness is adequately supported by the substantial equivalence information, materials data, and test results provided in this Premarket Notification.

- Viral Inactivation Validation
  The methods for processing the DBM contained in DynaGraft II were evaluated for their viral inactivation potential. A select panel of viruses representing various virus types, sizes, shapes, and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing methods for a wide range of potential human viruses.

- Osteoinductivety Potential
  The osteoinductive potential of the DBM used in DynaGraft II is determined via an *in vitro* assay. The assay measures the alkaline phosphatase activity of myoblast cells. The level of alkaline phosphatese induction is compared to positive and negative DBM controls. Results from the assay were correlated with results from implantation of DBM into an athymic rat muscle pouch. Analysis of these results shows that the *in vitro* assay has been validated against the *in vivo* athymic rat model and predicts with at least 95% confidence the *in vivo* osteoinductivity of the test material. 67 out of 67 test lots that passed the *in vitro* assay passed the *in vivo* athymic rat assay via confirmation of intramuscular bone formation.

  Each lot of DBM incorporated in the DynaGraft II is evaluated for osteoinductive potential using an *in vitro* assay. Testing each lot of DBM assures that only DBM with ostoeinductive potential is used in DynaGraft II. Although DBM used in the final product has been shown to be osteoinductive using an *in vitro* assay, the combination of DBM and inert carrier has not been evaluated for osteoinductivity; therefore, it is unknown to what extent the formulation components may alter the osteoinductivity character of the DBM. Additionally, it is unknown how osteoinductivity of the DBM component, measured via the *in vitro* assay, will correlate with human clinical performance of DynaGraft II.

- Product Performance Testing
  Performance of DynaGraft II DBM has been evaluated in rabbit and sheep models by radiographic and histological methods for the indications specified in the Premarket Notification.

Clinical studies using DynaGraft II DBM Putty and Gel have been performed for spinal fusions demonstrating acceptable outcomes.

These data substantiate DynaGraft II Putty and Gel safety and effectiveness for the indications presented in this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Mr. Paul Donor
Director of Quality Assurance and
Regulatory Affairs
IsoTis Orthobiologics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K040419
DynaGraft II Gel and DynaGraft II Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: January 5, 2005
Received: January 7, 2005

Dear Mr. Doner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

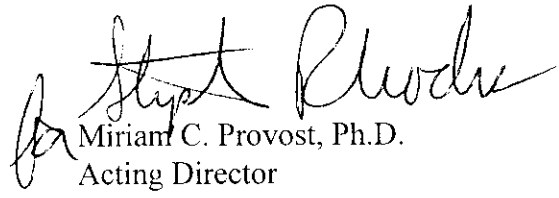
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040419

Device Name: DynaGraft® II Gel and Putty

Indications for Use:

DynaGraft® II is indicated for orthopedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. DynaGraft® II is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine, pelvis) and as bony void filler of the extremities and pelvis. These defects may be surgically created or from the result of traumatic injury to the bone.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K040419

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number_____